REMARKS

Applicants appreciate the indication by the Office that the finality of the rejections of the previous Office Action have been withdrawn. Claims 1-9, 11-13, 15-25, 27, 29, 35-37, 40, 41 and 43-48 are rejected under 34 U.S.C. §103 from Babayan et al. U.S. Patent No. 4,952,606 in view of Heydinger et al. "Medium Chain Triacylglycerols" and further in view of Wester U.S. Patent No. 6,589,588 and C.F.R. §101.83.

The present Amendment revises the single independent composition claim, the single method-for-making independent claim, and the single independent method-for-using claim. Each such claim specifies that the oil compositions are vegetable oil compositions in which the interesterified liquid structured lipid component is an **all-vegetable** component. In addition, each independent claim specifies that this vegetable oil composition of the liquid structured lipid and the phytosterol ester component **reduces cholesterol adsorption** in individuals.

In addition, dependent claim 45 is cancelled, the subject matter thereof having been incorporated into independent claims 37 and 40, the subject matter specifying reducing LDL cholesterol adsorption by the individual.

The Office recognizes that the structured lipid of Babayan is a reaction of dairy fat with medium-chain fatty acids. Thus, Babayan teaches one of ordinary skill in the art away from an all-vegetable structured lipid component. Concerning the statement at lines 2-3 on page 3 of the Office Action, the solution presented by Babayan to offset promotion of higher cholesterol is to transesterify dairy fat rather than use an all-vegetable component.

Concerning Heydinger, Table 2 on page 256 does not provide data for an all-vegetable interesterified structured lipid. Instead, the Neobee® 1814 product is disclosed in the first paragraph of page 256 of Heydinger as being "an MCT derivative made by interesterifying MCTs with butter oil." This is not the structured lipid claimed by applicants.

Concerning Wester, applicants continue to acknowledge that phytosterol esters are known for lowering cholesterol in a living being, as well as to incorporate same into foods. Applicants further acknowledge that Wester indicates that phytosterols *per se* can be incorporated into cooking oil. Applicants acknowledge that the C.F.R. section relates model health claims that may be placed on food labeling. The daily dietary intake levels found at page 147 of the C.F.R. publication regulate minimum amounts (1.3 grams) of phytosterols in daily dietary intake to make the health claim specified on that page. On balance, the C.F.R. publication adds regulatory details that are not particularly relevant to applicants' invention *vis-à-vis* Wester.

It is understood that the Office takes the position that a *prima facie* case of obviousness has been presented in the Office Action. In direct response, applicants provide the following information to indicate an enhanced unexpected benefit when one compares LDL cholesterol data from clinical testing with applicants' invention when compared with published data from a clinical study that corresponds to applicants' study but uses a different composition having the phytosterol.

The latter clinical study is found in reference DD in the Information Disclosure Statement considered by the Examiner on January 11, 2007. This is St.-Onge et al. "Consumption of a Functional Oil Rich in Phytosterols and Medium-Chain Triglyceride

Oil Improves Plasma Lipid Profiles in Men." Data in this St.-Onge publication show a reduction in LDL cholesterol, when compared to the baseline, of 14%. Data of the clinical study using applicants' claimed invention are found in the presently attached 2006 publication of Rudkowska et al. "Phytosterols Mixed with Medium-chain Triglycerides and High-oleic Canola Oil Decrease Plasma Lips in Overweight Men." The data from this later clinical study using applicants' claimed invention show a reduction in LDL cholesterol when compared with the baseline of 21%.

More particularly, the 2006 Rudkowska publication (applicants' claimed composition and methods) and the 2003 St. Onge publication each report on clinical testing of men having a body mass index of 25-31 kg/m^2. Twenty-three of these men completed the study using applicants' invention, while thirty men were in the study of the 2003 St.-Onge publication. Each study followed a randomized crossover type of test, and each delivered the phytosterol-containing component with the same isoenergetic meal protocol of 15% protein, 40% fat and 45% carbohydrates. In the 2006 clinical study according to applicants' claimed invention, blood samples were taken at days 1, 2, 41 and 42, whereas in the 2003 St.-Onge clinical study, blood samples were taken at days 1, 28 and 29. Each analyzed the blood samples and calculated LDL cholesterol using the Friedenwald formula.

The baseline LDL for applicants' invention was 3.95, same being reduced to the end point value of 3.12, a reduction of 21%. *See* data in the table on page 393 in the "Functional Oil" columns and the "LDL-C" rows. As reported in Table 3 on page 1817 of the St.-Onge publication, the baseline for the functional oil (FctO) for LDL-C was 3.43, and the Endpoint was 2.96, a reduction of 14%. Thus, the claimed invention achieved

an increase of 7% in LDL cholesterol reduction when compared with the St.-Onge clinical study. This represents an enhancement by a factor of one-third.

This enhancement is unexpected when one considers that the principal difference between the compositions of applicants' and of the compositions of the St.-Onge publication is that St.-Onge, although an all-vegetable oil composition of an MCT with a long chain fatty acid, does not interesterify these two components before blending with the phytosterol component. The Office has recognize that intersterification using MCT oils was previously known. However, a reference such as newly cited Babayan teaches same using a dairy fat component as opposed to a vegetable oil component. Inasmuch as Babayan recognizes that dairy fat components are associated with elevating cholesterol levels, the St.-Onge publication can be considered closer to applicants' (when considering cholesterol lowering) than would Babayan, the primary reference of the present Office Action.

Applicants respectfully observe that the above comparison of the St.-Onge data with the Rudkowska data using applicants' invention show a surprising improvement over an all-vegetable composition (St.-Onge) which is, in that respect, closer to applicants' claimed invention than the presently cited references.

Reconsideration and withdrawal of this §103 rejection are respectfully requested.

Respectfully submitted,

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